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No. 97-336

IN THE
SUPREME COURT OF THE UNITED STATES
OCTOBER TERM, 1997

UNITED STATES EX REL. PAMELA A. BERGE,
Petitioner,

v.

UNITED STATES OF AMERICA,
Intervenor-Respondent,

and

THE BOARD OF TRUSTEES OF THE UNIVERSITY OF ALABAMA AT BIRMINGHAM, ROBERT F. PASS, SERGIO B. STAGNO, CHARLES A. ALFORD, AND KAREN B. FOWLER,
Respondents.

ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

BRIEF FOR EUGENE DONG, M.D. J.D., ROBERT L. SPRAGUE, PH.D., A.C. HIGGINS, PH.D., AND JOHN S. GARDENIER, D.B.A. AS AMICI CURIAE IN SUPPORT OF PETITIONER

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17 pp

TABLE OF CONTENTS

TABLE OF AUTHORITIES ..... -ii-

INTEREST OF AMICI CURIAE ..... -1-

SUMMARY OF ARGUMENT ..... -2-

ARGUMENT ..... -4-

Congress Intended That *Qui Tam* Relators Play a Greater Role in Ferreting Out Fraud through The 1986 Amendments to The False Claims Act ..... -4-

Congressional Investigations Show Repeatedly That Science Misconduct By Federal Grantees Is Exposed by the Testimony of Other Scientists and Not of Agency Officials. ..... -7-

Under The Standard of Reviewing All the Evidence for Sufficiency of the Evidence in Scientific False Claims Cases Courts Impermissibly Select and Weigh Expert Scientific Testimony. ..... -11-

CONCLUSION ..... -14-

TABLE OF AUTHORITIES

Daubert v. Merrell Dow Pharmaceutical, Inc. 43 F.3d 1311, 1311 (Cir. 9th, 1995) ..... -11-

Daubert v. Merrell Dow Pharmaceuticals, 509 U.S. 579 (1993) ..... -4-, -11-, -12-

STATUTES

31 U.S.C. 3729 *et seq.*, ... -4-

OTHER AUTHORITIES

Biomedical Fraud Hearings"); *Are Scientific Misconduct and Conflicts of Interest Hazardous to Our Health? Nineteenth Report by the Committee on Government Operations, U.S. House of Reps.*, 101st Cong. 2 (1990) ..... -7-, -10-, -11-

Fraud in Biomedical Research: Hearings Before the Subcomm. On Investigations & Oversight, U.S. House of Reps., 97th Cong. 1 (1981) ..... -7--9-

H. R. Rep. 99-660 ..... -5-

S. Rep. No. 99-345 ..... -5-, -6-

This brief was authored in whole by counsel for *amici curiae* and no monetary contribution was received from anyone other than *amici curiae* or their counsel.

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INTEREST OF AMICI CURIAE

Amici curiae Eugene Dong, M.D., J.D., Robert L. Sprague, Ph.D. and Albert C. Higgins, Ph.D. are tenured faculty members of public and private universities who have been principal investigators of the National Institutes of Health and other private and public research funding agencies. Amici have

served as consultants to the Federal Government in various capacities including as peer reviewers of research grant applications. John S. Gardenier D.B.A. is a scientist employed by a government agency but joins this amicus brief in his capacity as a private citizen.

Amici Dong and Sprague have been complainants, litigants and/or counsel in administrative and legal proceedings concerning misrepresentation of scientific information. Amici Dong, Sprague and Higgins have published on the subject matter. Amicus Sprague has testified before three committees of Congress and has received an academic freedom award from the American Association for the Advancement of Science for his activities in this area. Dr. Gardenier has been active in various science ethics fora for several years; he has a strong interest in the emergence of a more consistent legal and ethical approach to defining and resolving allegations of scientific misconduct.

Amici have an interest in the procedural standards for reviewing the sufficiency of scientific evidence submitted by expert witnesses in scientific false claims cases.

II. SUMMARY OF ARGUMENT

The 1986 Amendments to the False Claims Act effected an important expansion in the kinds of cases of fraud against the government which may be litigated by enlarging the *qui tam* plaintiff's role in the litigation process. The statute brings to the

bar parties like petitioner Berge having the scientific expertise necessary to guide substantively the course of litigation in science fraud cases on behalf of the United States. The United States has been disadvantaged in other contexts in which a complaining scientist acts only as a mere expert consultant, if that, to lay government counsel or an agency official. The United States is positioned to more successfully recover funds for false claims made through, *inter alia*, misrepresentations or omissions of scientific information in a grantee's applications for public funds because of the increased role for the scientist in *qui tam* litigation.

As illustrated by the case herein, the issues which are litigated include claims made about scientific methodology and substantive scientific facts which in turn will require the admission of expert scientific testimony. In addition, expert testimony of scientists is relevant to evaluate the effect of statements on the funding decisions of the involved decision-making body, because the decision making body in this case, the National Institutes of Health, relies upon panels of "peer" reviewers for content analysis.

The district court admitted several expert scientific witnesses on behalf of the United States and relator Berge, including relator Berge herself. Amici suggest that since the admission of expert scientific testimony means that a Court has already determined that the reasoning or methodology underlying

the testimony is scientifically valid and that the reasoning or methodology properly can be applied to the facts in issue, *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993), it is counter-intuitive for a Court to hold that no reasonable jury could have found for the side which won based upon that admitted expert testimony.

With this case's scientific context in mind, amici respectfully suggest that it is an appropriate vehicle for review of the standards for challenging the sufficiency of evidence. Is the standard used by the Court of Appeals for the Fourth Circuit too broad so as to permit courts to review not only the admissibility of scientific testimony but also to impermissibly weigh the significance of that testimony to the case?

III. ARGUMENT

A. Congress Intended That *Qui Tam* Relators Play a Greater Role in Ferreting Out Fraud through The 1986 Amendments to The False Claims Act

Through the *qui tam* provisions of the amended False Claims Act, 31 U.S.C. 3729 *et seq.*, Congress intended to improve and encourage the participation of private citizens in combating fraud against the government: "The purpose of the qui tam provisions of the False Claims Act is to encourage private individuals who are aware of fraud being perpetrated against the

Government to bring such information forward." H. R. Rep. 99-660 at 23. *See also*, S. Rep. No. 99-345, at 2, ("The proposed legislation seeks not only to provide the Government's law enforcers with more effective tools, but to encourage any individual knowing of Government fraud to bring that information forward. In the face of sophisticated and widespread fraud, the Committee believes only a coordinated effort of both the Government and the citizenry will decrease this wave of defrauding public funds. S. 1562 increases incentives, financial and otherwise, for private individuals to bring suits on behalf of the Government.")

One of the major considerations for encouraging assistance from private citizens was the mismatch between government resources and defendants' resources brought to bear on any particular case:

"Taking into consideration the vast amount of Federal Dollars devoted to various complex and highly regulated assistance and procurement programs, Federal auditors, investigators, and attorneys are forced to make "screening" decisions based on resource factors. Allegations that perhaps could develop into very significant cases are often left unaddressed at the outset due to a judgment that devoting scarce resources to a questionable case may not be efficient. And with current budgetary constraints, it is unlikely that the Government's

corps of individuals assigned to anti-fraud enforcement will substantially increase.

"An additional problem noted by hearing witnesses, exists when large, profitable corporations are the subject of a fraud investigation and able to devote many times the manpower and resources available to the Government. This resource mismatch was recognized by DOD Inspector General Joseph Sherick who said that in far too many instances the Government's enforcement team is overmatched by the legal teams major contractors retain.

"The Committee believes that the amendments in S. 1552 which allow and encourage assistance from the private citizenry can make a significant impact on bolstering the Government's fraud enforcement effort." S. Rep. No. 99-345, at 7-8.

Another major consideration was the observation that the private citizen had access to the necessary information to bring suit: "Detecting fraud is usually very difficult without the cooperation of individuals who are either **close observers** or otherwise involved in the fraudulent activity." S. Rep. No. 99-345, at 4 (emphasis provided).

Finally, Congress noted that "most fraud goes undetected due to the **failure of Governmental agencies** to effectively ensure accountability on the part of program recipients and Government contractors." S. Rep. No. 99-345, at 3 (emphasis provided).

B. Congressional Investigations Show Repeatedly That Science Misconduct By Federal Grantees Is Exposed by the Testimony of Other Scientists and Not of Agency Officials.

Scientific misconduct by grantees of the United States is not a new phenomenon. Congress' concerns about scientific misconduct is reflected in a number of hearings on the problem since 1981. *Fraud in Biomedical Research: Hearings Before the Subcomm. On Investigations & Oversight, U.S. House of Reps.*, 97th Cong. 1 (1981) (Hereinafter, "*Biomedical Fraud Hearings*"); *Are Scientific Misconduct and Conflicts of Interest Hazardous to Our Health? Nineteenth Report by the Committee on Government Operations, U.S. House of Reps.*, 101st Cong. 2 (1990) H. R. Rep. No. 101-688. (Hereinafter, "*Scientific Misconduct Report*").

In what should be an intuitive observation, the reports show, *inter alia*, that the accused investigators were exposed by the investigations of their expert scientific colleagues.

In one case, the perpetrator, Dr. John Long testified: "Rather than repeat the biochemical experiments in an attempt to resolve the question, I resubmitted the paper and included falsified results that were consistent with expected findings. The paper was then accepted for publication. ¶ During the fall of 1979, Dr. Steven Quay, **an expert biochemist and colleague in the laboratory**, concluded that these experiments were not

performed as reported in the publication. Because I denied the charge, Dr. Quay discussed the matter with the chairman of the pathology department of the Massachusetts General Hospital. Because of my wrongdoing and dishonesty when confronted with the charges, I was asked to resign my position on January 31, 1980." *Biomedical Fraud Hearings* at 55-56 (Statement of Dr. John Long)(emphasis provided).

In another, unsuspected falsified data were found after the perpetrators were accused of plagiarizing a manuscript submitted for review. Dr. Philip Felig, then professor of medicine at the Yale University School of Medicine, testified: "Of particular note is the fact that the original audit of February 1980 took place as a result of allegations made one year earlier **by two [scientific] investigators from the NIH**. They alleged that the work in the Soman-Felig paper on anorexia nervosa had been plagiarized from a paper of theirs to which I had access as a reviewer for a medical journal. During that review process I had shown the NIH paper to Dr. Soman asking for his assistance in the evaluation of the manuscript." *Biomedical Fraud Hearings* at 87 (Statement of Dr. Philip Felig) (emphasis provided).

At the same hearing, the then associate director for Extramural Research and Training, William F. Raub, Ph.D., admitted that the National Institutes of Health's ("NIH) fraud investigations were geared towards business management issues.

Biomedical Fraud Hearings at 170 (Statement of Dr. William F. Raub). Indeed, NIH's investigators were individuals "whose background and training are primarily in areas of audit function, with strength in fiscal and financial accounting, but with broader experience and training in the general discipline of investigations." *Biomedical Fraud Hearings* at 176 (Testimony of Dr. William F. Raub).

Dr. Raub further acknowledged that "Fraudulent research practices present a different set of problems. In the first place, the process by which such violations are discovered is quite different. It has been NIH's experience that derogatory information is typically brought to light not by an agency administrator or auditor, but by **an institutional colleague**, a member of the public, or through the validation processes built into scientific publications." *Biomedical Fraud Hearings* at 170 (Statement of Dr. William F. Raub)(emphasis provided).

A number of cases were detailed in 1990 including "plagiarism, fabricating data, misrepresenting the way the study was conducted to minimize the flaws of the study, minimizing the risks of an experimental drug to patients who were asked to participate in the research, and reporting results that were considered either 'overly optimistic' or incorrect **by their colleagues**, in situations that put patients at risk." *Scientific Misconduct Report* at 10 (emphasis provided).

Again the frauds were brought to light by scientific colleagues intimately involved with the studies. One example in the report concerned the efforts of amicus curiae Robert Sprague, Ph.D. in the case of Dr. Stephen Breuning.

In 1983, Dr. Sprague, a senior colleague of psychologist Stephen Breuning who was conducting research on drug treatment for retarded children with behavior disorders, became suspicious of Dr. Breuning's work because of certain details of time allotment. In response to Dr. Sprague's request, Dr. Breuning failed to show Dr. Sprague any of the raw data for a study Dr. Breuning was about to report on at a conference. After raising the issues with the National Institute of Mental Health ("NIMH"), Dr. Sprague spent more than 1,000 hours of his time and several thousand dollars to set the record straight, when the NIMH investigators investigated him as well as Dr. Breuning. However, by 1988, Dr. Breuning plead guilty in Federal court to criminal charges for falsifying his research. *Scientific Misconduct Report* at 11 - 15.

The Committee on Government Operations also reported that in 1988 the National Institutes of Health scientific fraud office consisted of three staff members, two of whom had no training as auditors, investigators or scientists. Further, " witnesses describe PHS [public health service] investigations as superficial; investigators sometimes interviewed only the person

accused of wrongdoing and the 'whistle-blower,' without interviewing any other knowledgeable colleagues. Typically, no attempts were made to look at the data that held the key to the investigation." *Scientific Misconduct Report* at 7 - 8.

C. Under The Standard of Reviewing All the Evidence for Sufficiency of the Evidence in Scientific False Claims Cases Courts Impermissibly Select and Weigh Expert Scientific Testimony.

This Court has firmly established the role of courts in admitting scientific testimony. *Daubert v. Merrell Dow Pharmaceuticals,* 509 U.S. 579 (1993). The process entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue. *Daubert* at 509 U.S. 592 - 593. Courts have rightly been hesitant to analyze and evaluate scientific theories and data because they are "largely untrained in science and certainly no match for any of the witnesses whose testimony" they are reviewing. *Daubert v. Merrell Dow Pharmaceutical, Inc.* 43 F.3d 1311, 1316 (Cir. 9th, 1995). Chief Justice Rehnquist admitted that he was "at a loss to know what is meant when it is said that the scientific status of a theory depends on its 'falsifiability.'" *Daubert,* at 509 U.S. at 600, Rehnquist, C.J.,

dissenting. Nonetheless, once the process is completed, the result of a court's admission of an offered expert's testimony means that a very significant hurdle has been jumped. An expert's opinion is deemed reliable because it is presumed that it has a reliable basis in the knowledge and experience of his/her discipline. *Id.* at 592. Thus admitted expert testimony stands on a different footing from testimony from lay persons.

Relator Berge proffered the testimony of several expert witnesses, including herself, none of whom were challenged by the Court of Appeal pursuant to *Daubert*. In the view of these amici scientists, it is counter-intuitive to admit the testimony of scientific expert witnesses and then assert that there was insufficient evidence on which a reasonable jury would find for the winning side.

The Court of Appeals overturning of the jury's verdict comes about because the Court picked and chose among the expert witnesses who testified at trial. The Court of Appeals treated all of relator's expert witnesses as if they did not exist. Pet. 14. The opinion considered none of them. Yet, these are just the people who are responsible under NIH's scheme for initiating the funding decisions of the NIH, as the program official responsible for "shepherding" the grant through the review process admitted: "The reviews included technical evaluation of the merits of the Program Project by NIH constituted study

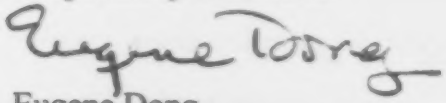
groups whose members consist of **other scientists in the same or related fields**. The peer review included in-person or telephonic 'site-visits' for the purpose of having the investigators answer questions regarding any aspects of their studies." J.A. 1510-1511. Instead the Court relied on the NIH program officer, who was not a peer reviewer.

Moreover, the Court of Appeal proceeded to select the facts it presumed were relevant to counter relator Berge's expert testimony regarding the scientific utility of UAB's computerization efforts as if she, an unknown graduate student, were a lay witness. Pet. 13a. Relator Berge qualified as an epidemiologist whereas Respondent Alford for example admitted that he only "dabbled in epidemiology'. J.A. 477. Morever, respondent Fowler herself did not use the University's disputed database and proceeded by abstracting medical records all over again. Opp. 6.

CONCLUSION

Amici curiae respectfully request the Court to consider the above additional relevant matters in support of granting the Petition.

Respectfully submitted



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